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Cohort Study

A prospective study on the incidence of sore throat after use of laryngeal mask airway during general anesthesia☆

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ABSTRACT

Background: Laryngeal mask airway (LMA) is a useful alternative to intubation of the trachea to maintain the airways. The aim of this study was to evaluate the incidence of sore throat after LMA during general anesthesia in short-duration elective surgery.

Method: In this prospective study, 76 patients undergoing surgery with general anesthesia in (XXX) during 2018 and 2019 were selected and their demographic information were entered into the data collection form. Laryngeal mask airway was used in the subjects for airway maintenance during the surgery. The incidence of sore throat at postoperative 0, 6, 12 h was measured using Visual Analogues Scale (VAS) as primary outcome and it was then compared with demographic parameters as secondary outcomes.

Result: The mean age of the patient was 45.48 ± 14.89 years and 46 (60.5 %) of the patients were women. The mean BMI was 24.02 ± 3.05 kg/m^2. The average duration of surgery was 56.9 ± 15.9 min. The incidence of sore throat immediately after the surgery and at 6 and 12 postoperative hours was 26.3 %, 23.7 %, and 19.7 %, respectively. The incidence of sore throat after the use of LMA was not significantly correlated with age, sex, and BMI ($P > 0.05$)

Conclusions: The findings of our study showed that pain due to sore throat following laryngeal mask airway was reported to be mild in our study. The postoperative sore throat may not associated with demographic variables.

1. Introduction

Tracheal intubation is one of the invasive procedures used in patients undergoing surgery that causes many problems for patients in the postoperative phase [1]. Although tracheal intubation is largely successful the consequences of doing so are sometimes very dangerous and life threatening [2,3].

Hemodynamic changes occur after direct laryngoscopy and further increase in heart rate and blood pressure occurs following endotracheal tube implantation [4,5]. To reduce hemodynamic alteration in direct laryngoscopy and intubation, the depth of anesthesia can be increased. The use of N_2O can also be useful [6]. The use of regional anesthesia has is effective in reducing hemodynamic changes [7]. However, due to the stimulatory effects that result from direct laryngoscopy and endotracheal intubation (ETT), these changes are fewer when laryngeal masks are used, since it does not stimulate the trachea [8]. One of the relatively common complications after intubation is sore throat, which is caused by damage to the throat during intubation and is seen in 26 % cases [9,10] and reduces the quality of surgery and results in patient dissatisfaction [11].

In patients under general anesthesia, laryngeal mask airway (LMA) method is used as an alternative to endotracheal intubation to maintain the airway, and its use had been increased. The LMA method was designed in 1981 and is superior to ETT in terms of no tracheal damage during insertion and removal of the tube, less airway stimulation, less invasion of airway tissue, easier implantation and airway establishment [12,13]. Relative to endotracheal intubation, LMA has greater incidence of sore throat, however the intensity of sore throat may be mild and might not affect the choice of LMA [14].

We hypothesized that incidence of sore throat following LMA would

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be less, and would be associated with reduced postoperative throat pain and greater patients' satisfaction. Furthermore, demographic variables like gender, age and BMI are likely to affect the incidence of postoperative sore throat [15–17]. In this study we investigated the incidence of sore throat after laryngeal mask surgery under general anesthesia and the factors affecting it in elective surgeries among patients referred to (XXX).

2. Method

In this interventional study, all patients with American Society of Anesthesiology Physical Status Classification (ASA) I-II, undergoing elective surgery under general anesthesia in (XXX) during 2018 and 2019 were enrolled. The patients underwent surgery where laryngeal mask airway method was used for general anesthesia. The study was approved by research ethics committee (XXX).

The incidence of sore throat, in terms of pain during speaking, at postoperative hours 0, 6 and 12 were obtained using visual analogue scale (VAS). Patients (men and women weighing 50–70 kg) were admitted after evaluation before anesthesia and assurance of at least 8 h of NPO (nothing by mouth). The procedure was explained to all the patients and written consent was obtained prior to the participation in the study.

2.1. Inclusion and exclusion criteria

Patients who underwent single elective surgery during the study duration were included in the study. Patients who didn't consent to participate, those with latex allergy, requiring emergency surgery, allergic to general anesthesia, previous maxillofacial and intraoral surgery and family history of previous malignant hyperthermia were excluded from the study.

2.2. Procedure

Patients who underwent single elective surgery during the study duration were included in the study. Patients who didn't consent to participate, those with latex allergy, requiring emergency surgery, allergic to general anesthesia, previous maxillofacial and intraoral surgery and family history of previous malignant hyperthermia were excluded from the study.

After entering the operating room and performing the necessary monitoring including NIBP (non-invasive blood pressure), ECG (electrocardiography) and pulse oximetry, 500 ml of normal saline was administered intravenously, as per surgery protocol. 3 μg/kg fentanyl and 0.03 mg/kg midazolam were injected and after 5 min of preoxygenation with 100 % oxygen, thiopental sodium 5 mg/kg anesthesia was induced. Due to the type of surgery and the short duration (less than 120 min) of surgery, muscle relaxants were not required.

In all patients, according to weight, LMA No. 3 (Tuoren, Xinxiang, China) was used and was inserted with the help of lidocaine-free lubricant gel. The cuff was completely deflated before the insertion and was inserted with digital intraoral manipulation. The cuff pressure was 40cmH_2O, monitored by manometer and oropharyngeal leak pressure was maintained within the normal range (25–35 cm H20). The position of LMA was established based on the visualization of more than high vocal cords. Maximum three attempt were made to position the device, and in case of need of alternative method, patients were excluded from the study. Patients were supported by a 10 cc/kg tidal vol; mechanical ventilator with a respiration rate of 10 beats per minute and measured by a capnograph to prevent hypercapnia. For all patients, sevoflurane & N2O + O2 (50.50 %) was used as maintenance anesthesia. Patients were also monitored for traumatic insertion of LMA at the time of extubating, indicated by the presence of blood on LMA or apparent damage to lips, teeth or gums.

2.3. Primary and secondary endpoints

Vital signs were monitored and recorded every 5 min during anesthesia. At the end of the surgery, the LMA was removed after regaining spontaneous breathing and relative consciousness. The patient was transferred to recovery unit and vital signs were monitored every 15 min and the pain intensity immediately after the surgery was obtained. If the patient's pain was moderate to severe (score 5 or higher on VAS), analgesia was prescribed, and the patient was excluded from the study. At discharge, the patient's sore throat was questioned and recorded by VAS method; after transfer to the relevant ward, 6 and 12 h later, the patient's sore throat was re-evaluated. Hoarseness was clearly explained to all the patients, in order to differentiate it with soreness (changes in voices to harsh or strained).

2.4. Statistical analysis

The data was collected by trained residents, who were the part of research team.

Data analysis was performed in SPSS V25. The outcomes were presented as descriptive and inferential findings. In the descriptive analysis for quantitative variables, mean and standard deviation was used, and for qualitative variables, absolute and relative frequencies were recorded in the form of graphs and tables. Kolmogorov–Smirnov test showed that the distribution of data related to the quantitative variable in this study is not a function of the normal distribution (p-value <0.05) Therefore, we use non-parametric tests (Mann-Whitney, Kruskal-Wallis, Spearman) to determine the relationships. To analyze the relationships in the inferential findings section, the following statistical tests were used: Mann-Whitney test, Kruskal-Wallis test and Pearson Correlation Coefficient. P value < 0.05 was considered to be statistically significant.

This study was approved by the Research Ethics Board of (XXX). Researchregistry6908.

The work has been reported in line with the STROCSS criteria [18].

3. Results

The subjects were in the age range of 13–80 years with a mean of 14.89 ± 45.48 years. 2.8 % of the subjects were under 20 years old, 11.1 % were between 21 and 30 years old, 30.6 % were between 31 and 40 years old, 19.4 % were between 41 and 50 years old, 15.3 % were between 51 and 60 years old and 20.8 % were over 60 years old. 46 (60.5 %) of the total patients' population were women.

The subjects were in the weight range of 50–70 kg with an average of 65.3 ± 5.6 kg. The subjects were in the height range of 141–187 cm with an average of 163.1 ± 9.3 cm. The average BMI of the patients was 24.4 ± 3.02 kg/m^2 (range 16.9–32.4). The mean duration of the surgery was 56.5 ± 14.6 min (range 30–92 min). According to ASA (American

Table 1
Investigate the distribution of data related to quantitative variables.

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	df	Sig.
Age	0.110	68	0.042	0.979	68	0.323
Weight	0.154	68	0.000	0.823	68	0.000
Height	0.255	68	0.000	0.629	68	0.000
BMI	0.466	68	0.000	0.227	68	0.000
The amount of sore throat immediately before leaving recovery	0.405	68	0.000	0.589	68	0.000
Sore throat immediately after 6 h	0.429	68	0.000	0.574	68	0.000
Sore throat immediately after 12 h	0.460	68	0.000	0.527	68	0.000
Duration of surgery	0.271	68	0.000	0.848	68	0.000

Society of Anesthesiologists) classification, 78.1 patients were classified in ASA I and 21.9 % in ASA II class (Table 1). The most common procedures performed were fistula surgery in 13.1 %, hernia in 19.6 %, carpal tunnel syndrome and breast surgery in 9.2 %, respectively (Table 2).

The frequency of sore throat immediately after entering recovery ward and 6 and 12 h after the surgery was 26.3 %, 23.7 % and 19.7 %, respectively. Considering the 5 % calculation error, it can be said that the prevalence of sore throat after laryngeal mask use immediately after, 6 and 12 h after the surgery was 16.5 %–36.1 %, 13.6 %–33.3 % and 10.7 %–28.7 %, respectively. Pain scores were reported after laryngeal mass surgery under general anesthesia based on the 10 cm VAS scale immediately before leaving recovery, after 6 and 12 h, 1.1 ± 1.5 cm, 0.8 ± 1.4 cm and 0.6 ± 1.3 cm, respectively.

The incidence of sore throat after laryngeal mask surgery under general anesthesia based on age (Table 3).

The incidence of sore throat after laryngeal mask surgery under general anesthesia based on gender (Table 4).

Spearman correlation test showed that there was no significant relationship between the intensity of sore throat after laryngeal mask surgery under general anesthesia and age of the patients, P-value = 0.829, 0.563, 0.620, respectively. The intensity of the sore throat at these three intervals were also not significantly associated with BMI, P-value = 0.119, 0.309 and 0.471, respectively. The gender was also not associated significantly with postoperative sore throat at any interval, $p > 0.05$(Table 5).

4. Discussion

Postoperative sore throat is caused by mechanical trauma to mucosa as a result of intubation that leads to inflammation [19]. Our study reported mild postoperative sore throat following LMA among patients who underwent surgery with general anesthesia. The intensity pain was not associated with gender, BMI and age of the patients at 0, 6 and 12 postoperative hours. In ETT, due to small size of the tube, the incidence of sore throat is reported to be greater in female patients [20]. A study by Ahmed, Abbasi [21] showed that in advanced age increased the risk of postoperative sore throat following ETT. Whereas, Higgins, Chung [22] showed that young age is a risk factor. Our study showed that sore throat following LMA is not associated with age. Intubation can also be difficult in morbidly obese individuals and the size of LMA is likely to affect the outcomes in over weight and obese patients [23].

The overall incidence of sore throat after the surgery at different intervals was lesser compared to other studies [10], however it also depends on factors such as cuff pressure [24], lubrication of the cuff, type of anesthesia, gender and size of the tube [25,26]. In the interventional study by Safaeian et al. [27] 171 patients were included where they received laryngeal mask or endotracheal intubation. There was no significant difference in the frequency of sore throat among the two group. 44.2 % patients in tracheal intubation were presented with sore throat. However, hoarseness, shortness of breath and cough were significantly more in tracheal intubation group. Similar findings were reported in the study by Jaensson, Gupta [28]. The results showed that 32 % sore throat complication was reported in LMA group and 57 % in endotracheal tube group. Peirovifar et al. conducted a study on 80

Table 2
Distribution of individuals by type of surgery.

		Frequency	%	Valid percentage
Type of surgery	Abdominoperineal resection (APR)	2	2.6	2.6
	APR repair/Tubectomy	1	1.3	1.3
	Carpal tunnel syndrome	7	9.2	9.2
	CYSTO URETRO SEOPY	1	1.3	1.3
	Dilation and curettage (D&C)	2	2.6	2.6
	Tubectomy	1	1.3	1.3
	Transurethral lithotripsy (TUL)	2	2.6	2.6
	Transurethral resection of the prostate (TURP)	1	1.3	1.3
	Perianal abscess	1	1.3	1.3
	Hand nerve release	1	1.3	1.3
	Endometriosis	1	1.3	1.3
	temporal artery biopsy	1	1.3	1.3
	Thoracoscopic biopsy	1	1.3	1.3
	Breast biopsy	1	1.3	1.3
	Rectal prolapse	1	1.3	1.3
	Chest tube	1	1.3	1.3
	duct stenosis	1	1.3	1.3
	Axillary lymph nodes	1	1.3	1.3
	Hand Ganglion	2	2.6	2.6
	Thigh Ganglion	1	1.3	1.3
	Underarm Ganglion	1	1.3	1.3
	Breast mass	7	9.2	9.2
	Toe surgery	1	1.3	1.3
	Foreign Body Removal	1	1.3	1.3
	Fistula	10	13.1	13.1
	Bartholin's cyst	2	2.6	2.6
	Conization	1	1.3	1.3
	Bunion	1	1.3	1.3
	Hernia	14	19.6	19.6
	Hemorrhoids	1	1.3	1.3

Table 3
The incidence of sore throat after laryngeal mask surgery under general anesthesia based on age.

			The amount of sore throat after leaving recovery	Sore throat 6 h after surgery	Sore throat 12 h after surgery
Spearman's rho	Age	Correlation coefficient	0.026	0.069	0.059
		p-value	0.829	0.563	0.620
		number	76	76	76

Table 4
The incidence of sore throat after laryngeal mask surgery under general anesthesia based on gender.

Report				
Sex		The amount of sore throat after leaving recovery	Sore throat 6 h after surgery	Sore throat 12 h after surgery
Female	Mean	1.65	1.41	1.33
	Number	46	46	46
	Standard deviation	1.233	.884	0.668
Male	Mean	1.33	1.33	1.15
	Number	27	27	27
	Standard deviation	0.679	0.620	0.362
Total	Mean	1.53	1.38	1.26
	Number	73	73	73
	Standard deviation	1.068	0.793	0.578

Table 5
Spearman correlation test to determine the incidence of sore throat after laryngeal mask surgery under general anesthesia based on body mass index.

		The amount of sore throat after leaving recovery	Sore throat 6 h after surgery	Sore throat 12 h after surgery
BMI	Correlation coefficient	0.186	0.121	0.086
	P-value	0.119	0.309	0.471
	Number	76	76	76

receiving either laryngeal mask or endotracheal tube during low-flow anesthesia with controlled ventilation. The postoperative complications such as cough, sore throat and difficulty in swallowing were significantly greater in endotracheal group [29]. In a study, L'Hermite and colleagues examined the occurrence of sore throat following the use of a laryngeal mask. For this purpose, 546 patients underwent elective surgery with a duration of general anesthesia of less than 2 h where 23.9 % of the subjects had sore throat [30]. Chinachoti et al., evaluated risk factors for sore throat following surgery under general anesthesia, and 2503 people were included in the study. The study concluded that postoperative sore throat is correlated with postoperative hoarseness and is significantly greater in endotracheal intubation patients [17]. In a recent single-blinded trial, Gong, Xu [31] assessed the incidence of sore throat in patients after thyroid surgery. Postoperative sore throat was significantly greater in endotracheal intubation group, along with alterations in blood pressure and heart rate. Buckling was also greater in intubation patients.

In our study, there was no significant relationship between the incidence of sore throat and age, sex and BMI. In the study by Grady et al. large and small were placed Large LMA for size 5 men and size 4 for women, respectively. Based on the results of this study, it was concluded that there was no significant difference between the two sexes in terms of sore throat with LMA of both the sizes [32]. In a systematic review, El-Boghdadly et al. examined the sore throat following general anesthesia and reported that LMA-associated postoperative sore throat is greater in children and endotracheal intubation is a preferable method [16].

4.1. Limitations and future recommendation

Our study does not evaluate the other complications like dysphagia and odynophagia associated with LMA. The findings of this study are merely based on pain during speaking. Furthermore, we do not compare our outcomes with endotracheal intubation and hemodynamic parameter. Future studies are recommended with larger sample size, variable demographics and more parameters. We also suggest that pediatric, adult and geriatric groups should be separately assessed in this regard.

5. Conclusion

Our study reported mild postoperative sore throat immediately after the surgery and at 6 and 12, postoperative hours among patients undergoing elective surgery under general anesthesia. The incidence of sore throat was not associated with gender, age and BMI of the patients.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Availability of data and material

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

Declaration of competing interest

The authors deny any conflict of interest in any terms or by any means during the study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2021.102595.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Sources of funding

No funding was secured for this study.

Author contributions

Dr. kourosh Farazmehr and Dr. Seyed Sepideh Hosseini: conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr.Mohamad Aryafar and Dr. Giti Dehghanmanshadi: Designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript.

Dr. Farshid Gholami: Coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content.

Registration of research studies

1. Name of the registry: Tehran Islamic Azad University of Medical Sciences.
2. Unique Identifying number or registration ResearchRegistry: 6908.
3. Hyperlink to the registration (must be publicly accessible): https://www.researchregistry.com/browse-the-registry#home/registrationdetails/60ce59d3083536001f618c76/

Guarantor

Dr. kourosh Farazmehr.

Consent

Not applicable.

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